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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,060	01/04/2002	Andrew Koff	14538A-005111US	5760

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EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,060	KOFF ET AL.	
	Examiner	Art Unit	
	Louis D. Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on 6/05/2006 is acknowledged. Claims 1-11 are pending. Claims 1 and 2 were amended. Claims 1-11 are under consideration. An action on the merits follows.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/05/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are newly rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims have been amended so that they now contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original disclosure fails to recite the negative limitation of "non-xenogeneic thymocytes" (Claim 1). Further, the original

disclosure fails to recite the limitation of "obtaining from the animal a sample of hematopoietic cells and positively identifying a subpopulation thereof as thymocytes" (Claim 1). Applicants have not indicated where in the specification **implicit or explicit** support for these limitations can be found. Based on the disclosure as filed a practitioner in the art would not be able to determine that the inventors contemplated the negative limitation of "non-xenogeneic thymocytes"" or the limitation of "obtaining from the animal a sample of hematopoietic cells and positively identifying a subpopulation thereof as thymocytes," at the time of filing. Further, a key word search of the specification fails to find disclosure of these limitations anywhere in the specification as initially filed. Therefore, since the specification as filed doe not contain support for the phrases "non-xenogeneic thymocytes"" or "obtaining from the animal a sample of hematopoietic cells and positively identifying a subpopulation thereof as thymocytes," they are considered to be new matter. See M.P.E.P. 608.04(a). Claims 2-11 depend from claim 1.

The rejection of claims 1-11 under 35 U.S.C. 112, first paragraph for lack of because the specification did not enable the full breadth of the claims is withdrawn in view of applicants amendments to the claims.

Claim Rejections - 35 USC § 102

The rejection of claims 1-11 under 35 U.S.C. 102(e) as being anticipated by Roberts JM et al (US Patent No 5,958,769, dated 8-28-99, filing date 1-18-1996), is withdrawn in view of applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts JM et al (US Patent No 5,958,769, dated 8-28-99, filing date 1-18-1996), in view of Lopez et al. {Lopez et al. (1993) Int J. Immunopharmac 15 :899-907}.

Roberts et al. provides guidance on an ex vivo method, wherein hematopoietic precursor cells are isolated from bone marrow (pgph 27). Further Roberts et al. teaches that endogenous gene encoding $p27^{Kip1}$ is altered by:

> a sequence comprising or encoding an oligonucleotide p27 inhibitor, e.g., triplex forming oligonucleotides, antisense oligonucleotide, ribozyme, etc., or a combination of such inhibitors targeted to different portions of the p27 DNA or corresponding RNA can be delivered in a wide variety of ways to targeted cells to facilitate progression of the cell cycle. The oligonucleotides can be administered as synthetic oligonucleotides or expressed from an expression vector. (pgph 15).

Wherein the synthesized oligonucleotides may be introduced into suitable cells by a variety of means including electroporation or microinjection (pgph 9). Roberts et al. also provides guidance on the use of a plasmid pPNT containing the neomycin resistance gene and the thymidine kinase gene. Roberts et al. teaches that after the cell population treated with $p27^{Kip1}$ inhibitor is transduced or transfected ex vivo the cells are cultured with a selection agent such as neomycin used in the vector, and then may be returned to the host or expanded until a sufficient number of cells are available for return to the host (pgph 25). Roberts et al. teaches that inhibition of $p27^{Kip1}$ produces hypercellularity of the spleen and thymus in mice (see lines 30-37

in column 19). Roberts et al. teaches that the examined thymus and spleen were twice as large as control mice and that counts of nucleated cells from the spleen and thymus confirmed the hypercellularity of these tissues. Roberts et al. does not provide guidance on positively identifying a subpopulation of hematopoietic cells as thymocytes.

Lopez et al. supplements the guidance of Roberts et al. by teaching a method of isolating nucleated cells from the spleen or thymus, and identifying and quantifying CD4+ and CD8+ T-cell subpopulations by immunofluorescent tagged antibodies and FACS analysis (pg. 900, col. 2-pg. 901, col. 1).

Based on the guidance provided by Lopez et al. on positively identifying a subpopulation of hematopoietic cells as thymocytes, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to modify the teachings of Roberts et al. by positively identifying and quantifying the subpopulations thymocytes isolated from the thymus with immunofluorescent tagged antibodies and FACS analysis.

A practitioner in the art would be motivated to modify the teachings of Roberts et al. with the teachings of Lopez et al. because FACS analysis is a more accurate and precise method of identifying specific cell types such as a subpopulation of thymocytes than microscopic evaluation and manual counting of nucleated cells.

The person of ordinary skill in the art would have had a reasonable expectation of success because positively identifying and quantifying the subpopulations thymocytes isolated from the thymus with immunofluorescent tagged antibodies and FACS analysis would have been routine in the art at the time of filing.

No claims allowed.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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